10108881

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 002415woMegn	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP00/09241	International filing date (*day/month/year*) 21 September 2000 (21.09.00)	Priority date (*day/month/year*) 21 September 1999 (21.09.99)
International Patent Classification (IPC) or national classification and IPC C07K 14/705		
Applicant AFFINA IMMUNTECHNIK GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 01 March 2001 (01.03.01)	Date of completion of this report 10 January 2002 (10.01.2002)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP00/09241

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:
pages 1-17, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:
pages 1-12, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the sequence listing part of the description:
pages 1-6, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☒ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1, 5-12 (in part).

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV.

The following document is considered below:

D3 = ELIES R ET AL.: "STRUCTURAL AND FUNCTIONAL ANALYSIS OF THE B CELL EPITOPES RECOGNIZED BY ANTI-RECEPTOR AUTOANTIBODIES IN PATIENTS WITH CHAGAS' DISEASE", JORNAL OF IMMUNOLOGY (1996 NOV 1) 157(9) 4203-11, XP002142657.

(The numbering of the document corresponds to its order in the sequence found in the international search report.)

PCT Rule 13.1 states that a common inventive idea must be present to satisfy the criterion of unity of invention.

In the context of the present patent application, peptides are produced that bind to autoantibodies that cause DCM.

The present application indicates that corresponding peptides are already known from prior art; however, in contrast with the present invention, those peptides, coupled to a solid phase, are not capable of binding and eliminating the corresponding autoantibodies from the blood plasma of a patient.

However, document D3 describes peptides that are similar to epitopes of the ß1-adrenoceptor, of the ß2-adrenoceptor, and of M2-acetylcholine as well as affinity purification of the corresponding autoantibodies from patient serum made possible by these peptides. In

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV.

particular, a peptide of the ß1-adrenoceptor (HWWRAESDEARRCYNDPKCCDFVTNR) was successfully used therein that differs only minimally from one of the two peptides (HWWRAESDEARRSYNDPKC) used in the present application.

Since no additional "special technical feature" (PCT Rule 13.2) could be found, unity of invention is lacking. The peptides described in the present patent application must accordingly be considered to be different inventions.

Furthermore, in the context of the present patent application, trials with only two peptides (TGSFFCELWTSGKK and HWWRAESDEARRSYNDPKC) are described; however, the present claims comprise peptides that are not necessarily derived therefrom and potentially are entirely different, variations of individual amino acid positions going far beyond conservative amino acid exchange. Hence, an effect according to the invention is entirely doubtful for the majority of the peptides falling under Claim 1 and is not supported by corresponding examples; on the other hand, the wealth of possible combinations does not make meaningful examination possible. The examiner is also concerned that, owing to the closeness of the prior art (D3), every variation of the peptides of the application would have to be considered as an independent invention.

Accordingly, the following inventions can be identified in the present application:

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV.

I) a peptide with the sequence TGSFFCELWTSGKK

II) a peptide with the sequence HWWRAESDEARRSYNDPKC.

Correspondingly, the claims of this application can be divided into the following groups:

1) Claims 1, 5-12 (exclusively) related to a peptide with the sequence TGSFFCELWTSGKK;

2) Claims 1-12 (exclusively) related to a peptide with the sequence HWWRAESDEARRSYNDPKC.

In response to the request for limitation or for payment of additional fees, the applicants desire examination of the subject matter identified as invention I. The present report thus covers Claims 1 and 5-12 exclusively with respect to a peptide with the amino acid sequence TGSFFCELWTSGKK.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1, 5-12	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1, 5-12	NO
Industrial applicability (IA)	Claims	1, 5-12	YES
	Claims		NO

2. Citations and explanations

Novelty under PCT Article 33(2)

2) In the prior art (e.g., document D3), peptides have already been identified that have similar technical properties (e.g., the possibility of binding and, consequently, removing autoantibodies), such as the peptide of the application with sequence TGSFFCELWTSGKK. However, since no peptide with the same sequence is described in the prior art, novelty can be acknowledged for Claims 1 and 5-12 to the extent these claims refer to a peptide with the sequence TGSFFCELWTSGKK.

Inventive step under PCT Article 33(3)

3) The present peptide represents an alternative to the peptides already described in the prior art (D3). When searching for such alternatives, a person skilled in the art would produce additional peptides of the ß1-adrenoceptor according to the knowledge in document D3 and examine this for its suitability for binding autoantibodies.

Although production of such peptides and their

corresponding examination requires a certain degree of effort, it does not exceed the standard methodology available to a person skilled in the art. In the absence of an unexpected effect, which differentiates the present peptide from similar peptides such as are described in D3, an inventive step cannot be recognized for the production of same. Hence, Claims 1 and 5-12 do not correspond to PCT Article 33(3).